

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA**

THE CITY OF HUNTINGTON,

Plaintiff,

v.

AMERISOURCEBERGEN DRUG
CORPORATION, et al.,

Defendants.

Civil Action No. 3:17-01362
Hon. David A. Faber

CABELL COUNTY COMMISSION,

Plaintiff,

v.

AMERISOURCEBERGEN DRUG
CORPORATION, et al.,

Defendants.

Civil Action No. 3:17-01665
Hon. David A. Faber

**REPLY MEMORANDUM IN SUPPORT OF
DEFENDANTS' MOTION FOR SUMMARY JUDGMENT
ON PROXIMATE CAUSATION GROUNDS**

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INTRODUCTION

For three separate reasons, Plaintiffs' Opposition fails to overcome Defendants' entitlement to summary judgment on proximate causation grounds.

1. Plaintiffs' Opposition rests on a fundamental misunderstanding of West Virginia law: that to establish proximate causation, a plaintiff need only prove a defendant's actions contributed to or foreseeably led to harm. *See* Opp. 5. Plaintiffs are wrong. It is well-established that "remoteness is a component of proximate cause" under West Virginia law,¹ which requires proof of a **direct relation** between a plaintiff's alleged injuries and the defendant's alleged misconduct.² That directness requirement is **distinct from foreseeability** and applies even if Plaintiffs can demonstrate that Defendants' alleged wrongdoing contributed to or foreseeably led to Plaintiffs' alleged injuries.³

As Defendants established in their opening brief, any connection between their alleged wrongdoing and Plaintiffs' alleged injuries is too attenuated and remote to establish proximate causation. Plaintiffs offer **no evidence** in response to that showing. Although Plaintiffs allege that Defendants' shipments resulted in a "flood" of prescription opioids in Cabell/Huntington, that does not establish proximate causation. Even accepting *arguendo* that such a "flood" occurred,

¹ *Aikens v. Debow*, 208 W. Va. 486, 492 (2000).

² *Employer Teamsters-Local Nos. 175/505 Health & Welfare Trust Fund v. Bristol Myers Squibb Co.*, 969 F. Supp. 2d 463, 475 (S.D. W. Va. 2013) (Chambers, C.J.); *see also City of Charleston v. Joint Comm'n*, 2020 WL 4116952, at *22 (S.D. W. Va. July 20, 2020) (Copenhaver, J.).

³ *See, e.g., Hemi Grp., LLC v. City of New York, N.Y.*, 559 U.S. 1, 12 (2010) (noting "[t]he concepts of direct relationship and foreseeability are ... two of the many shapes proximate cause took at common law"); *City of Charleston*, 2020 WL 4116952, at *22–26 (discussing foreseeability and directness as separate components of proximate cause and dismissing for lack of a sufficiently direct relationship).

Defendants' shipments still are too remote from any harms suffered by Plaintiffs as a matter of law. Even if Defendants "flooded" pharmacies with pills, the medications would have sat on a shelf, causing harm to no one, but for the intervening acts of (1) doctors who wrote opioid prescriptions for their patients, (2) pharmacists who dispensed opioid medicines to patients, (3) third-party criminals who diverted opioid medicines to illicit use, and (4) end-users who criminally used opioids for a non-medical purpose.⁴ Under established precedent, the intervening conduct of these numerous independent actors conclusively demonstrates the absence of proximate causation as to Defendants.

2. Separate and apart from the remoteness problem discussed above, Plaintiffs cannot show that Defendants' alleged conduct caused the harms that they allege. Although the Opposition cites numerous expert reports and deposition transcripts in an attempt to create the appearance of disputed issues of fact, it cites no evidence that Defendants proximately caused Plaintiffs' harms. Instead, the evidence Plaintiffs cite falls into three main buckets—none of which is sufficient to establish proximate causation:

- Plaintiffs purport to have evidence that Defendants violated the federal Controlled Substances Act ("CSA") and West Virginia Controlled Substances Act ("WVCSA") (collectively, the "Acts"). But that evidence does not establish causation. To prove proximate causation, it is not enough for Plaintiffs to show that Defendants violated duties purportedly imposed under the Acts, or that Defendants should have conducted greater "due diligence" regarding pharmacy orders. Rather, Plaintiffs must present evidence that (1) Defendants' allegedly

⁴ There is no dispute that Defendants shipped medicines only to licensed dispensaries in Cabell/Huntington. Nor is there any claim that any medicines were directly diverted while in Defendants' possession and under their control. Rather, Plaintiffs' claims are premised entirely on the diversion of medicines after they were delivered by Defendants to DEA-registered pharmacies and hospitals and after they were dispensed by those pharmacies and hospitals.

deficient due diligence caused a “flood” of pharmacy orders to be distributed that otherwise would not have been and (2) those orders proximately caused Plaintiffs’ alleged injuries. Plaintiffs’ Opposition does not even attempt to make either evidentiary showing.

- Plaintiffs point to an alleged “flood” of prescription opioids distributed to pharmacies and hospitals in Cabell/Huntington, but they have no evidence that Defendants were the proximate cause of that alleged “flood.” To the contrary, Defendants’ wholesale business is, by definition, reactive. Defendants fill aggregate orders placed by DEA-registered pharmacies and hospitals, which in turn are based on prescriptions written by State-licensed medical professionals. Although Plaintiffs claim that, in retrospect, many of those prescriptions were not medically necessary, they have no evidence of any prescriptions—and, in turn, orders or groups of orders—that were contrary to the then-prevailing standard of care. Wholesale distributors have no duty or ability to police prescribing by doctors or to prevent patients from receiving the medicines prescribed in good faith by their doctors, and Plaintiffs have no evidence that additional diligence would have reduced the aggregate supply of opioids in Cabell/Huntington.
- Plaintiffs point to evidence of an association between (1) an increase in the number of opioids available in a community and (2) increased instances of opioid use disorder and other opioid-related harms in that community. But even if Plaintiffs could prove a causal connection between opioid supply and opioid-related harms, that would not satisfy Plaintiffs’ burden here. As described above, the record evidence demonstrates that Defendants were not the cause of the increase in the number of opioids available: they do not control the supply of prescription opioids made available to patients in Cabell/Huntington and are not responsible for second-guessing the good-faith prescribing decisions of doctors in Cabell/Huntington. Absent a

showing that Defendants’ wrongful conduct caused the increase in supply, Defendants cannot be liable for the alleged harms—even if Plaintiffs prove that the increase in supply was a direct and immediate cause of their alleged injuries (which they have not done).

3. Finally, Plaintiffs have no evidence that Defendants played any role whatsoever in distributing illegal, non-prescription opioids into Cabell/Huntington. Accordingly, it is especially clear that Defendants were not the cause—let alone a direct and immediate cause—of any injuries arising from the use of heroin and illicit fentanyl by Cabell/Huntington residents.

ARGUMENT

I. PLAINTIFFS CANNOT PROVE A DIRECT RELATION BETWEEN DEFENDANTS’ ALLEGED WRONGDOING AND THEIR ALLEGED INJURIES.

Plaintiffs’ principal argument—that they need not prove a “direct relation” between Defendants’ alleged wrongdoing and their purported injury, *see* Opp. 5–6—is incorrect as a matter of settled West Virginia law. Because Plaintiffs cannot (and do not even attempt to) establish such a direct relation, Defendants are entitled to summary judgment.

A. Plaintiffs Cannot Escape the Requirement of Proving a “Direct Relation.”

The Opposition argues (1) that proximate causation turns solely on whether Defendants’ conduct “contribute[d] in any degree” to Plaintiffs’ alleged injury and (2) that “foreseeability,” standing alone, is enough to withstand summary judgment. Opp. 5–6. Both arguments are wrong.

It is well-established in West Virginia that “remoteness is a component of proximate cause.” *Aikens*, 208 W. Va. at 492. This consideration of remoteness “embraces the concept that the judicial remedy cannot encompass every conceivable harm that can be traced to alleged wrongdoing.” *Id.* Thus, the conduct “which renders a defendant liable for damages must be a

proximate, **not a remote**, cause of injury.” *Metro v. Smith*, 146 W.Va. 983, 124 S.E.2d 460, 464 (1962).⁵

The Supreme Court explained the remoteness standard in *Holmes v. Securities Investor Protection Corp.*, 503 U.S. 258, 268 (1992), holding that proximate cause requires, *inter alia*, “a **direct relation** between the injury asserted and the injurious conduct alleged.” That requirement is **not** RICO-specific, but rather derives from the “common-law foundations” of proximate cause. *Hemi Grp., LLC v. City of New York, N.Y.*, 559 U.S. 1, 9 (2010) (plurality opinion); *Holmes*, 503 U.S. at 268 (noting that directness is “among the many shapes [proximate cause] took at common law”).

Consistent with the principles articulated in *Aikens*, *Metro*, and *Holmes*, courts in this District repeatedly have applied the *Holmes* “direct relation” standard to West Virginia state-law claims. *See, e.g., Employer Teamsters-Local*, 969 F. Supp. 2d at 475 (Chambers, C.J.) (discussing *Holmes* and applying the “direct relation” standard to West Virginia state law claims); *City of Charleston*, 2020 WL 4116952, at *22 (Copenhaver, J.) (discussing *Holmes* and concluding that “courts have applied the principles of remoteness to state law tort claims insofar as proximate cause requires carefully drawing a line so as to distinguish the **direct consequences** in a close causal chain from more attenuated effects influenced by too many intervening causes”). Accordingly, it is not enough for Plaintiffs to demonstrate that Defendants’ conduct “contributed” to their alleged injuries in some remote fashion, or that their alleged injuries were “foreseeable”—Plaintiffs also must demonstrate a “direct relation.”

⁵ All emphases added unless otherwise noted.

The cases cited in the Opposition do not hold differently. As an initial matter, many of those cases do not address the legal standard for proximate cause, but instead address the types of evidence that courts may consider in assessing whether proximate cause is satisfied.⁶ The rest of Plaintiffs' cases do not involve the question of directness and remoteness presented here. Instead, they address the separate question of establishing proximate causation in the context of concurrent negligence—*i.e.*, situations “[w]here separate and distinct negligent acts of two or more persons continue unbroken to the instant of an injury, contributing ***directly and immediately thereto.***” *Wehner v. Weinstein*, 191 W. Va. 149, 155 (1994).⁷ In those cases, the question is not whether the defendant’s conduct was too remote to constitute a proximate cause, but rather whether the concurrent direct negligence of a third party should cut off or offset the defendant’s liability.⁸ Here, the conduct of doctors in prescribing, of pharmacies in dispensing, of patients and others in

⁶ See *Huskey v. Ethicon, Inc.*, 2015 WL 4944339, at *6 (S.D. W. Va. Aug. 19, 2015), *aff’d*, 848 F.3d 151 (4th Cir. 2017) (concluding that “[p]roximate cause can be established either by direct evidence or by circumstantial evidence” but not addressing the legal standard for proximate cause); *BCS Servs., Inc. v. Heartwood 88, LLC*, 637 F.3d 750, 754–56 (7th Cir. 2011) (discussing evidence relevant to cause-in-fact but explicitly noting that the doctrine of proximate cause—which “eliminates some actual or possible but probably minor causes as grounds of legal liability”—“has no application to this case”); see also Restatement (Second) Torts § 443B, cmt. b (addressing the burden of proof for causation and discussing different means by which a plaintiff might present evidence to satisfy that burden).

⁷ See *Gillingham v. Stephenson*, 209 W. Va. 741, 744 (2001) (defendant directly rear-ended plaintiffs’ car); *Wehner v. Weinstein*, 191 W. Va. 149, 153 (1994) (defendant’s car directly hit and killed plaintiff after third-party released handbrake); *Perry v. Melton*, 171 W. Va. 397, 399 (1982) (defendant directly hit and killed plaintiff after crossing median while driving drunk); *Everly v. Columbia Gas of W. Virginia, Inc.*, 171 W. Va. 534, 535 (1982) (defendant’s gas transmission equipment leaked, directly causing explosion).

⁸ For similar reasons, Plaintiffs’ citation of various “intervening act” cases misses the point. Opp. 6. Defendants do not argue that the independent actions identified in their opening briefs are “intervening acts” that break off proximate causation, but rather that their alleged misconduct is too remote to constitute a proximate cause as a matter of law. Similarly, Defendants do not dispute that there can be more than one proximate cause of an injury—the problem here is that Plaintiffs have not come forward with *any evidence* that Defendants are a proximate (*i.e.*, direct) cause of their alleged injuries.

diverting, and of end-users in abusing opioids is not concurrent (or parallel) conduct, but a series of steps that separates Defendants' conduct from Plaintiffs' alleged harm.

As described above and in Defendants' opening brief, it is well-established that, irrespective of any other requirement, directness is a necessary element of proximate cause. Judge Copenhaver's recent decision in *City of Charleston v. Joint Commission* is instructive. There, Huntington and other municipalities alleged that the defendant healthcare-accreditation organization's issuance of opioid-friendly treatment guidelines contributed to the opioid crisis. 2020 WL 4116952, at **3, 4. Although the court discussed foreseeability at length in determining whether the defendant owed plaintiffs a duty of care, *id.* at *15–19, its proximate cause analysis focused on whether there was a sufficiently direct connection between the alleged misconduct and alleged injuries, *id.* at *21–26; *see also id.* at *22 (“proximate cause requires carefully drawing a line so as to distinguish *the direct consequences* in a close causal chain from more attenuated effects influenced by too many intervening causes”). The court's focus on directness as an independent requirement of proximate cause is consistent with *Holmes* and its progeny, which make clear that the *Holmes* standard “turns on the *directness* of the resultant harm, not the *foreseeability* of that harm.”⁹

⁹ *Slay's Restoration, LLC v. Wright Nat'l Flood Ins. Co.*, 884 F.3d 489, 493 (4th Cir. 2018) (emphasis in original); *City of Cleveland v. Ameritrust Mortg. Secs.*, 615 F.3d 496, 502 (6th Cir. 2010) (“[T]he requirement of a direct injury is ... *distinct from foreseeability* and applies even if the Defendants intentionally caused the alleged course of events.”); *see also Anza v. Ideal Steel Supply Corp.*, 547 U.S. 451, 461 (2006) (concluding that when a court evaluates proximate causation under the *Holmes* standard, “the central question it must ask is whether the alleged violation led *directly* to the plaintiff's injuries”); *Hemi Grp., LLC v. City of New York, N.Y.*, 559 U.S. 1, 12 (2010) (noting that directness and foreseeability are “two of the many shapes proximate cause took at common law” and rejecting the argument that foreseeability, standing alone, is enough to satisfy proximate cause).

Plaintiffs’ reliance on the MDL court’s summary judgment decision is misplaced, for it applied different law to different facts in an entirely different case. *See* Opp. 1–2, 4, 6–7, 12–13, 16–19, 21. As the Sixth Circuit recently explained when granting a mandamus petition in the MDL, “a district court’s decision ... in an individual case depends on the record in *that case and not others*,” and a court may not “distort or disregard the rules of law applicable to each of those cases.” *Id.* at 841, 844–45. This principle applies with full force here, where adjudication of Defendants’ motion for summary judgment requires application of controlling West Virginia law and consideration of the factual record developed by Plaintiffs in this case—not “rote acceptance of the decision of a court outside the chain of direct review.” *In re Korean Air Lines Disaster*, 829 F.2d 1171, 1175 (D.C. Cir. 1987) (Ginsburg, J.).

Further, the MDL court’s decision is not persuasive authority because it applied a “substantial factor” and “foreseeability” standard for proximate causation that is contrary to settled West Virginia law. *See* Br. Ex. 1 at 9 (“a factfinder could reasonably infer [Defendants’] failures were a substantial factor in producing the alleged harm”); *id.* at 9 n.8 (“a jury could reasonably conclude diversion is a foreseeable consequence of the alleged misconduct”).¹⁰ The MDL court did *not* analyze or address the issues of remoteness and direct injury that are essential elements of proximate causation under West Virginia law. *See supra* Part I.A. The MDL decision thus did not apply—and did not even purport to apply—the standards of West Virginia law governing proximate causation.

¹⁰ The “substantial factor” and “foreseeability” standard applied by the MDL court also was contrary to controlling Ohio law—which, similar to West Virginia, requires a “direct relation” between the alleged misconduct and alleged injury. *See, e.g., Ameriquest*, 615 F.3d at 503 (noting that “the Ohio Supreme Court has adopted the Holmes Court’s proximate cause analysis”).

In sum, even if Plaintiffs could demonstrate that their injuries were a “foreseeable” consequence of Defendants’ conduct (they cannot), that would not relieve Plaintiffs of their burden to establish a “direct relation.” Because Plaintiffs’ Opposition (1) fails to address the controlling legal standard and (2) makes absolutely no effort to prove the requisite “direct relation,” it does nothing to rebut Defendants’ showing that they are entitled to summary judgment on causation grounds.

B. Plaintiffs Have Not Come Forward with any Evidence of a “Direct Relation.”

As explained above, Plaintiffs must establish a *direct relation* between Defendants’ conduct and their alleged injuries. *See, e.g., City of Charleston*, 2020 WL 4116952, at *22. Although Plaintiffs rely heavily on several decisions from other states sustaining similar claims at the motion to dismiss stage (Opp. 1 n.4), they cannot defeat Defendants’ summary judgment motion merely by *alleging* that Defendants’ conduct proximately caused their alleged injuries. Rather, Plaintiffs must come forward with evidence *establishing* that Defendants’ alleged failure to identify, report, and halt “suspicious” orders (the only allegedly wrongful conduct identified by Plaintiffs) was a direct cause of their injuries. *See* Br. 2–3. Plaintiffs have wholly failed to meet their burden.

Plaintiffs’ Opposition focuses on evidence of an alleged “flood” of prescription opioids. *See* Opp. 2–3, 9–10. According to Plaintiffs, summary judgment should be denied because Defendants shipped too many opioids into Cabell/Huntington. *Id.* But even if there was a “flood” of prescription opioids, and even if Defendants’ alleged regulatory failures caused an excess volume of shipments, that *still* does not (and cannot) establish proximate causation. As set forth more fully in Defendants’ opening brief, the record evidence makes clear that at least *four independent acts* stand between Defendants’ shipment of prescription opioid medicines to DEA-registered hospitals and pharmacies and any harm suffered by Plaintiffs. *See* Br. 4–6. Before the

medicines that Defendants delivered to hospitals and pharmacies could possibly have caused any addiction, overdose or death, (1) a physician must have exercised professional judgment to write a prescription and (2) a pharmacist must have exercised professional judgment to dispense the prescription. Thereafter, the medicines were either used by the patient to whom they were prescribed—in which case Distributors plainly cannot be liable for any resulting harm—or (3) diverted to illicit use, which may have involved several transactions, each of which, by definition, was a crime. Finally, before any harm can occur, (4) the diverted pills must be ingested by City or County residents—which is also a crime.

Put simply, regardless of whether Defendants shipped too many prescription opioids into Cabell/Huntington, those prescription opioids would have sat on pharmacies’ shelves, doing harm to no one, but for the independent conduct of numerous third- and fourth-party actors. Accordingly, Defendants’ alleged conduct is simply too remote from Plaintiffs’ alleged injuries as a matter of law to constitute a proximate cause—and that is true *even if* Defendants’ shipments resulted in the alleged “flood” in Cabell/Huntington.

This conclusion is reinforced by Judge Breyer’s recent decision in the *San Francisco* MDL case. There, Judge Breyer rejected the causal chain articulated by the MDL court (and relied on by Plaintiffs here) because it improperly “omit[ted] the city residents” who “ingested” opioids. *City & Cty. of San Francisco v. Purdue Pharma L.P.*, No. 3:18-CV-07591-CRB, 2020 WL 5816488, at *27 (N.D. Cal. Sept. 30, 2020). He further noted that it failed adequately to account for the intervening criminal acts separating Defendants’ alleged oversupply of prescription opioids and Plaintiffs’ alleged injuries:

The City’s causal chain ... involves too many links and depends on independent and intervening acts—including criminal conduct—by third and fourth parties. For example, third—and potentially fourth and fifth—parties allegedly diverted or sold illicit opioids While it is plausible that Defendants’ conduct enabled this third-

party behavior, *it is impossible to conclude that Defendants' conduct directly caused the City's harm* within the meaning contemplated by *Hemi*.

Id. at *24 (underlining emphasis in original). Thus, Judge Breyer concluded, “[t]he City’s causal chain resembles the chain rejected in *Hemi*: it involves too many links and depends on independent and intervening acts—including criminal conduct—by third and fourth parties.” *Id.* The same is true here.

Tellingly, Plaintiffs do not dispute that four intervening acts—including two or more crimes—stand between Defendants’ distribution of FDA-approved medicines to DEA-registered dispensaries and any potential harm they might suffer. Instead, Plaintiffs try to avoid that dispositive point by arguing that Defendants can be held liable so long as they were a “substantial contributing factor[.]” Opp. 15. Plaintiffs are wrong as a matter of well-established West Virginia law. *See, e.g., Aiken*, 208 W. Va. at 492 (“remoteness is a component of proximate cause”); *Metro*, 124 S.E.2d at 464 (conduct “must be a proximate, not a remote, cause of injury”).

The *City of Charleston* case demonstrates the point. There, as here, government entities tried to recover costs incurred responding to the opioid crisis from a defendant that was far removed from the actual harm—an organization that issued alleged opioid-friendly “Pain Management Standards.” 2020 WL 4116952, at ** 3, 4, 12. The court concluded that the plaintiffs’ state-law claims failed the *Holmes* “direct relation” test because “numerous intervening events and parties st[ood] between” the cities’ alleged injuries and the defendant’s conduct, including (1) “[t]he independent medical judgement of ... prescribing physicians” and (2) “criminal actions of third parties[] such as illegal drug traffick[ers].” *Id.* at *25.

Plaintiffs are wrong in suggesting that *City of Charleston* found “that a distributor’s conduct *was not* too attenuated” to establish proximate causation. Opp. 21 (emphasis in original). Rather, the court observed that the defendant in *City of Charleston*—a healthcare accreditation

organization—was even *further* removed in the causal chain than are wholesale distributors. But the court’s analysis of remoteness is squarely on point. The same independent actors whose intervening conduct defeated a showing of proximate causation in *City of Charleston* also establish the absence of proximate causation here. In this case, just as in *City of Charleston*, Plaintiffs’ alleged harm here was *directly* caused by the doctors who wrote allegedly inappropriate prescriptions and the criminal actors who improperly diverted and abused prescription opioids—not by Defendants. See *City of Charleston*, 2020 WL 4116952, at *25.

II. THERE IS NO EVIDENCE THAT DEFENDANTS’ ASSERTED FAILURE TO CONDUCT ADEQUATE DUE DILIGENCE CAUSED PLAINTIFFS’ INJURIES.

The points addressed above in Part I are dispositive on the issue of proximate causation. But, in addition, there is a separate, independent basis for summary judgment: Plaintiffs have no evidence that Defendants’ alleged conduct caused the “oversupply” or “flood” of which they complain in the first place. Br. 9–15. Thus, even putting aside the threshold remoteness problem discussed above, Plaintiffs cannot show that Defendants’ alleged conduct caused the harms that they allege. In response, Plaintiffs assert that they “offer considerable expert testimony, circumstantial evidence, and admissions” that purportedly create a triable question of fact. Opp. 9. But the “evidence,” to the extent any is cited at all, does not bear on whether Defendants’ conduct proximately caused Plaintiffs’ alleged injuries.

As previously discussed, Plaintiffs claim to have evidence of “high amounts of [prescription] opioid drugs flooding Plaintiffs’ communities.” *E.g.*, Opp. 9. But even assuming there was a “flood,” there is no evidence that Defendants proximately caused it. As set forth in Defendants’ opening brief, Defendants distribute FDA-approved medications to State-licensed, DEA-registered hospitals and pharmacies in response to orders based on the volume of prescriptions written by State-licensed medical professionals. Defendants (1) do not make

prescribing decisions, (2) cannot review or second-guess prescribing decisions, (3) do not dispense prescription opioids directly to patients, and (4) have no control over the prescription opioid medications they distribute after those medicines are shipped to DEA-registered hospitals and pharmacies. Br. 4–6. Thus, as Plaintiffs’ own experts have recognized, Defendants *do not determine the supply of prescription opioids that reach end-users in Cabell/Huntington*—medical professionals and illegal actors do.¹¹

Although Plaintiffs claim that, in retrospect, many of the opioids that doctors prescribed, customers ordered, and Defendants shipped (and which subsequently reached end-users through independent third-party conduct) were not medically necessary, wholesale distributors have no duty or ability to police prescribing by doctors or to prevent patients from receiving the medicines prescribed in good faith by their doctors pursuant to the prevailing standard of care. Br. 5, 13.

Plaintiffs nevertheless contend that Defendants shipped too many pills because they should have identified, reported, and refused to ship “suspicious” opioid orders. Opp. 7–12. But even if Defendants had a “duty” to report and stop shipment of some orders,¹² and even if that “duty”

¹¹ See, e.g., Ex. 1 (Keyes Tr.) at 115:16–116:6 (agreeing that the only way prescription opioid pills can leave a pharmacy and enter the community are through prescriptions written by doctors or illegal conduct); Ex. 2 (Ciccarone Tr.) at 217:10–219:6 (testifying that increased supply was “driven by increases in opioid prescribing practices” and that “supply doesn’t expand into the community unless the doctors write the prescriptions”).

¹² They did not. See generally Defendants’ Memorandum of Law in Opposition to Plaintiffs’ Motion for Partial Summary Judgment Concerning Defendants’ Statutory and Regulatory Duties (“Defs.’ Duties Opp.”) (Dkt. 1079); see also Memorandum in Support of Defendants’ Motion for Summary Judgment for Failure to Prove Fault Element of Public Nuisance Claims (“Defs.’ Fault Br.”) (Dkt. 1007-3) at 6–17; Memorandum of Law in Opposition to Plaintiffs’ Motion to Adopt MDL Court’s August 19, 2019 Order (Dkt. 235).

could be enforced by Plaintiffs,¹³ and even if Defendants violated that supposed “duty,”¹⁴ this does not establish that the asserted violation proximately caused harm to Plaintiffs. Instead, in order to demonstrate proximate causation, Plaintiffs must come forward with evidence establishing that materially fewer medicines would have been shipped had Defendants not violated their “duty.”¹⁵

Plaintiffs wholly fail to meet that burden. They do not identify even a *single instance* where either (i) adequate due diligence would have flagged a pharmacy order as improper or contrary to the *then-prevailing* standard of care or (ii) a shipment by any of Defendants resulted in diversion in Cabell/Huntington.¹⁶ Br. 11–15, 19–20. None of Plaintiffs’ experts addressed the question of which orders or what volume of orders reflected anything other than physician prescribing in accordance with the then-prevailing standard of care. Indeed, contrary to Plaintiffs’ suggestion, their experts admit that they (1) did not review any individual orders to determine if they were improper or contrary to prevailing standards of care;¹⁷ (2) do not know whether any

¹³ It cannot. *See* Defs.’ Fault Br. at 5–8; Defs.’ Duties Opp. 6 n.7.

¹⁴ They did not. *See, e.g.,* Defs.’ Duties Opp. 16–19; Cardinal Health’s Response to Plaintiffs’ Motion for Partial Summary Judgment Regarding Cardinal Health’s Compliance with the CSA (Dkt. 1087).

¹⁵ Nor do the so-called “admissions” on which Plaintiffs rely establish causation. Opp. 7–8, 11–12. For example, Plaintiffs cite testimony from Defendants’ employees agreeing that more opioid pills “could” increase the potential for diversion or that diversion “can happen” if Defendants violate laws. Opp. 11–12. But none of those supposed admissions suggests, much less demonstrates, that diversion occurred in Plaintiffs’ jurisdictions as a result of Defendants’ alleged excessive shipments or that improper shipments of opioids by Defendants caused Plaintiffs to incur a single penny of additional expense.

¹⁶ Plaintiffs claim that so long as the court can infer (using “aggregate proof”) that some orders shipped by Defendants were diverted, “it makes no difference which ones.” Opp. 17. That is incorrect. Because (i) not all orders were filled by these Defendants, (ii) not all orders filled by these Defendants were diverted, and (iii) not all diversion led to addiction, overdoses, or other problems, it is critical for Plaintiffs to show which orders were diverted and to tie those orders to specific alleged harms.

¹⁷ *See* Ex. 3 (Rafalski Tr.) at 87:21–88:2 (“Q. You’ve not reviewed each of those flagged orders; correct? A. No, sir. Q. Do you know how many of the tens of millions you’ve actually reviewed?

orders were diverted;¹⁸ and (3) cannot identify any orders that caused Plaintiffs any harm. Accordingly, Plaintiffs have no evidence that additional diligence by Defendants would have reduced the aggregate supply of opioids in Cabell/Huntington.¹⁹

The expert evidence to which Plaintiffs point either has nothing to do with causation or is disconnected from Defendants' alleged conduct. None establishes, even on an aggregate basis, that Defendants' purported failure to conduct adequate due diligence on "suspicious orders" proximately caused any injury to Plaintiffs:

A. Yes, *I have not reviewed any of them.*"); Ex. 4 (McCann Tr.) at 128:2–9 ("Q. Your flagging analysis does not identify the orders of opioids that should have been reported to DEA; correct? A. Correct. Q. As part of your flagging analysis, *you did not review defendants' customer diligence files; correct?* A. *Correct.*"); Ex. 5 (Keller Tr.) at 48:12–49:1 (agreeing that identifying suspicious orders is "beyond what [she] w[as] able to do and beyond [her] expertise").

¹⁸ See Ex. 3 (Rafalski Tr.) at 90:13–23 ("Q. Did you look at any of those tens of millions of orders ... to make a judgment that ... th[e] order is likely to be diverted? A. There—I *cannot definitively look at one specific order and tell you that specific order was diverted, if that's your question. I did not do that and I couldn't—I did not do that and I could not do that.*"); Ex. 4 (McCann Tr.) at 127:14–128:1 ("Q. Now, your flagging analysis, sir, does not identify the number of opioids that were diverted; correct? A. Correct. Q. Your flagging analysis does not identify the number of opioids that were unlawfully distributed; correct? A. Correct. Q. Your flagging analysis does not identify the number of opioids that were more likely than not to be diverted; correct? A. Correct."); Ex. 5 (Keller Tr.) at 168:11–14 ("Q. Are you offering the opinion that any of the ... prescription opioid medications reflected in any of your analyses were diverted? A. No, I'm not offering that opinion.").

¹⁹ Although Plaintiffs' experts identify a handful of pharmacy customers that had "suspicious" ordering patterns, thereby allegedly warranting further investigation by Defendants, neither Plaintiffs nor their experts identify (1) any orders placed by those pharmacies that further investigation would have determined to be, in fact, improper or (2) any instances in which one of those pharmacies or its customers diverted the prescribed pills, causing injury to Plaintiffs. Br. 14–15. As DEA itself has made clear, there is no basis to assume that an order flagged as "suspicious" is improper or at risk of diversion. See Ex. 6 (Wright MDL Dep.) at 208:5–24 (orders that meet regulatory definition of "suspicious" may well be "false positives" that do not pose a risk of diversion); Ex. 7 (Prevoznik MDL Dep.) at 307:18–308:2 ("Q. [If] an order that is unusually large, does that order necessarily lead to diversion? A. [I]t may or may not.").

- **Dr. McGuire.** Dr. McGuire purports to quantify Plaintiffs’ damages. He does not opine on, or support in any way, the proposition that Defendants’ conduct caused Plaintiffs’ injuries—he simply *assumes* that. Ex. 8 (McGuire Tr.) at 54:14–55:21.
- **Drs. Ciccarone, Keyes, Kolodny, Lembke, and Waller.** Plaintiffs claim that Drs. Ciccarone, Keyes, Kolodny, Lembke, and Waller establish a connection between the oversupply of prescription opioids in Cabell/Huntington and certain opioid-related harms. Opp. 13–14.²⁰ But the aforementioned experts do not provide any basis to conclude that Defendants were the proximate cause of that purported oversupply or any related harms.²¹ As previously noted, the record demonstrates that Defendants do not determine the supply of prescription opioids that reaches end-users in Cabell/Huntington. *See supra* 12–13. Thus, even assuming *arguendo* that there is a causal connection between the alleged oversupply and the injuries underlying Plaintiffs’ claims, that would not establish that *Defendants* were a proximate cause of those injuries.

²⁰ The fact that opioid medicines have the potential to be addictive and cause harm is not particularly controversial—it says as much in the FDA-approved labels for the medicines.

²¹ *See* Ex. 2 (Ciccarone Tr.) at 218:11–14, 244:11–22 (agreeing that “what the distributors shipped to pharmacies reflected what the doctors were prescribing” and that he has no evidence of distributors shipping more pills than what doctors prescribed); Ex. 1 (Keyes Tr.) at 300:5–301:4 (testifying that she does not have any expertise in suspicious order monitoring, has not reviewed any specific orders, has not reviewed any diligence files or investigative documents, and has not reviewed any documents relating to specific distributors’ activities); Ex. 9 (Kolodny Tr.) at 111:9–112:2, 116:13–117:2, 275:1–18 (testifying that he has no opinion as to the percentage of prescriptions that were legitimate or illegitimate, that he hasn’t performed a study to determine how many opioid pills were clinically warranted, and that he is not aware of any evidence showing distributors’ customers were filling prescriptions written by doctors who lacked an appropriate license); Ex. 10 (Lembke Tr.) at 161:1–8 (testifying that she did not review any of the distributors’ suspicious order monitoring systems or any specific orders shipped in Cabell/Huntington); Ex. 11 (Waller Tr.) at 164:15–165:9 (testifying that he has no opinion as to whether Defendants’ complied with their obligations or shipped any orders they shouldn’t have).

- **Ms. Keller.** Although Ms. Keller purports to identify certain high-volume prescribers in Cabell/Huntington, Opp. 10, she has no opinion as to whether those prescribers “were doing anything wrong” or whether the prescriptions they were writing were medically improper—certainly not improper under the then-prevailing standard of care. Ex. 5 (Keller Tr.) at 54:9–18, 154:23–155:7. She also has no opinion as to whether any of the prescriptions identified in her analysis were diverted. *Id.* at 168:11–14. In any event, wholesale distributors do not have any obligation or ability to second-guess the medical decisions of State-licensed prescribers.
- **Dr. McCann.** Dr. McCann calculated, using five different methodologies, the number of orders that Defendants purportedly *could have* flagged for further due diligence. Ex. 12 (McCann Rep.) ¶¶ 104–128. But contrary to Plaintiffs’ suggestion, Opp. 10, Dr. McCann has no opinion as to whether Defendants’ suspicious order monitoring programs were deficient, whether adequate systems and effective due diligence would have determined these orders to be, in fact, inappropriate under the then-prevailing standard of care for prescribing opioids, or whether any suspicious orders were shipped into Cabell/Huntington. Indeed, Dr. McCann concedes that he has no opinion as to whether (1) any of the five algorithms are capable of identifying “suspicious” orders as they were received, or (2) any of the orders he flagged were actually improper, diverted, or caused any harm. Ex. 4 (McCann Tr.) at 14:1–15:4, 100:19–101:10, 127:14–128:5.
- **Mr. Rafalski.** Mr. Rafalski opines that one of the five calculation methodologies used by Dr. McCann “provides a reasonable estimate and an initial trigger and first step to identifying orders of unusual size.” Ex. 13 (Rafalski Rep.) at 50. He does not, however, offer evidence that all—or any—of the orders meeting this “initial trigger” for further

due diligence would have been determined to be, in fact, problematic or were diverted to illicit use. To the contrary, Mr. Rafalski admits that he cannot determine how many orders (if any at all) were (1) actually improper, (2) diverted to illicit use, or (3) caused Plaintiffs any harm. *See supra* 14–15. Lacking any such knowledge, Mr. Rafalski cannot opine that Defendants’ shipments caused diversion—let alone caused Plaintiffs any harm. This conclusion is not altered by Mr. Rafalski’s unadorned belief—untethered to any facts or evidence—that “more likely than not[,] all of those [flagged] orders are diverted.” *See* Ex. 3 (Rafalski Tr.) at 90:24–91:15.

Put simply, Plaintiffs have no evidence—expert or otherwise—tying evidence of diversion in Cabell/Huntington to Defendants’ alleged misconduct, on the one hand, and to their alleged injuries, on the other hand.

III. THERE IS NO EVIDENCE THAT DEFENDANTS PROXIMATELY CAUSED ANY INJURIES ARISING FROM ILLEGAL, NON-PRESCRIPTION OPIOIDS.

Defendants’ opening brief also demonstrated that Plaintiffs have no evidence that Defendants proximately caused any of Plaintiffs’ alleged injuries arising from the abuse of illegal, non-prescription opioids such as heroin and illicit fentanyl. *See* Br. 15–17. Plaintiffs have no response to that argument, and cite no evidence that demonstrates a “direct relation” between Defendants’ distribution of FDA-approved prescription opioid medicines and any harms caused by illicit drugs.

Defendants do not supply illicit drugs—illicit drug trafficking organizations do. Br. 16 & n.25. Plaintiffs do not dispute this point. Instead, they argue that there is evidence of a “correlat[ion]” between prescription opioid supply and “rates of heroin and fentanyl use.” *See, e.g.* Opp. 12. But even if that were true (it is not), it does nothing to establish proximate causation *as to Defendants*. DEA-registered and State-licensed wholesale distributors like Defendants are

simply not part of causal chain for illicit opioid-related harm, and therefore cannot be considered even a remote cause of such harm. Moreover, any harm caused by the abuse of illegal drugs distributed by others is even further removed from Defendants' conduct than any harm caused by the misuse of the prescription opioids that Defendants distribute. Because the Opposition does nothing to disturb these inescapable conclusions, it is especially clear that Defendants are entitled to summary judgment insofar as Plaintiffs' alleged injuries are based on the abuse of illegal, non-prescription opioids by Cabell/Huntington residents.

CONCLUSION

Because there is no evidentiary basis on which a reasonable jury could conclude that Defendants proximately caused Plaintiffs' injuries, Defendants are entitled to summary judgment.

Dated: October 30, 2020

Respectfully Submitted,

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CERTIFICATE OF SERVICE

The undersigned counsel hereby certifies that on this 30th day of October, 2020, the foregoing “REPLY MEMORANDUM IN SUPPORT OF DEFENDANTS’ MOTION FOR SUMMARY JUDGMENT ON PROXIMATE CAUSATION GROUNDS” was served using the Court’s CM/ECF system, which will send notification of such filing to all counsel of record.

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